DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 30, 2015

VectraCor, Inc.
A.J. Schreck
Quality/Regulatory Manager
785 Totowa Road, Suite 100
Totowa, NJ 07512

Re: K140852
Trade/Device Name: Vectraplex CMS
Regulation Number: 21 CFR 870.2300
Regulation Name: System, Network and Communication, Physiological Monitors
Regulatory Class: Class II
Product Code: MSX, MLD, MHX
Dated: January 21, 2015
Received: January 23, 2015

Dear Mr. Schreck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Division Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140852

Device Name
Vectraplex CMS

Indications for Use *(Describe)*

- Vectraplex® CMS is a Central Monitoring System intended to transfer information between networked devices (only VectraplexECG Systems), which include hard-wired or wireless devices
- The Central Monitoring System can be used for remote monitor management, printing, viewing or otherwise processing of information from VectraplexECG Systems including remote control
- The device is intended to be used by qualified medical professionals
- The Vectraplex CMS will audibly and visually alarm if the VectraplexECG System's CEB® (VectraplexAMI), Cardiac Electrical Biomarker, reaches an alarm condition.
- The Vectraplex CMS' intended use population consists of those patients with certain medical conditions in whom continuous cardiac monitoring is considered to be a medical necessity in the judgment of the ordering healthcare provider.
- The Vectraplex CMS is intended for centralized monitoring of patients through a network in hospitals, Emergency Departments and Surgical Centers, doctor's offices, and urgent care facilities.
- Not for home use

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5. 510(k) Summary

510(k) Summary

As required per 807.92(c)

510(k) Notification

VectraCor's Vectraplex CMS

1. Submitters Name, Address:

Brad S. Schreck

VectraCor, Inc.

785 Totowa Road

Suite 100

Totowa NJ, 07512

Phone: 973-904-0444

Email: bschreck@vectracor.com

Official Correspondent: Brad Schreck, President

Contact Person for this Submission: Brad Schreck

Date submission was prepared: April 1, 2014

2. Trade Name, Common Name, and Classification Name:
   - Trade Name: Vectraplex CMS
   - Classification Name, Product Code, Classification and Regulation Number

Monitor, ST Segment with Alarm	MLD	Class II	870.1025
System, Network and Communication, Physiological Monitors	MSX	Class II	870.2300
Monitor, Physiological, Patient (with arrhythmia detection or alarms)	MHX	Class II	870.1025

3. Predicate Device Identification
   - Datex-Ohmeda S/5 Network and Central '02 – 510(k) K022507
   - Mindray North America DPM Central Station – 510(k) K080192

4. Device Description

The Vectraplex CMS is a program that can allow a central monitoring system to view multiple VectraplexECG Systems through either an intranet or internet connection. There are three programs to the central monitoring system: the Monitor Agent, the Device Agent, and the Proxy Agent. The programs require Java version 1.7 or higher prior to installation. The Monitor Agent will remotely display and control another device's screen. The Device Agent (installed on the bedside monitoring device) will allow the Monitor Agent (remote central monitoring system) to access the Device Agent's system and control it on demand. The Proxy Agent is a "behind the scenes" program installed on a computer or server, running Windows 7 operating system, which integrates multiple systems (central monitoring system, bedside monitors) and allows them to communicate. The Monitor and Device Agents connect through the use of the Proxy Agent by utilizing a singular IP address, either through the internet or the intranet. Due to the separation of the Proxy Agent from the other systems, communication may occur over both intranet as well as internet connections.

The maximum capacity of the Vectraplex CMS is a total of 16 devices. Each Proxy Agent can withstand a maximum load of 16 devices displayed on 3 different monitors. These 3 monitors are duplicates of the same 16 devices.

5. Indications for Use:

- Vectraplex® CMS is a Central Monitoring System intended to transfer information between networked devices (only VectraplexECG Systems), which include hard-wired or wireless devices
- The Central Monitoring System can be used for remote monitor management, printing, viewing or otherwise processing of information from VectraplexECG Systems including remote control
- The device is intended to be used by qualified medical professionals
- The Vectraplex CMS will audibly and visually alarm if the VectraplexECG System's CEB® (VectraplexAMI), Cardiac Electrical Biomarker, reaches an alarm condition.
- The Vectraplex CMS' intended use population consists of those patients with certain medical conditions in whom continuous cardiac monitoring is considered to be a medical necessity in the judgment of the ordering healthcare provider.
- The Vectraplex CMS is intended for centralized monitoring of patients through a network in hospitals, Emergency Departments and Surgical Centers, doctor's offices, and urgent care facilities.
- Not for home use

6. Comparison to Predicate Device:

The Vectraplex CMS is similar to the predicate devices:

- Datex-Ohmeda S/5 Network and Central '02 – 510(k) K022507
- Mindray North America DPM Central Station– 510(k) K080192

Comparison Between the Vectraplex CMS, the Mindray North America DPM Central Station, and Datex-Ohmeda S/5 Network and Central '02

Parameter	Vectraplex CMS	Datex-Ohmeda S/5 Network and Central '02	Mindray North America DPM Central Station
Computer Based System	Yes	Yes	Yes
Display Configuration	LCD Display	LCD Display	LCD display
Bi-directional Communication	Yes	No	Yes
Single Monitor Functionality	Yes	Yes	Yes
Dual Monitor Functionality	Yes	Yes	Yes
Analysis Program on Central Monitor	No. However, if monitoring the VectraplexECG System (which does analyses), and because the Vectraplex CMS duplicates the screen of that system, the CMS will display the analysis	Yes it has an analysis program	No. Requires a separate analysis program.
Transmit Data	LAN/WLAN	LAN/WLAN	PDS Gateway & HL7
Connection Protocol	TCP/IP	TCP/IP	TCP/IP
Stores Data	No	Yes	No
Environmental Conditions	Operating Temperature: 0°C - 35°C Non-Operating:-40°C - 65°C Relative humidity Operating: 20 R.H. to 80 R.H. Storage: 20 R.H. to 95 R.H.	Operating Temperature: 10°C - 35°C (50°F-95°F) Non-Operating: -- 10°C - 50°C (14°F-122°F)	Operating temperature 0°C to +45°C Non-operating temperature -20°C to +65°C Operating humidity 10% to 95% (non-condensing) Non-Operating humidity 5% to 95%
Power source	100-240 VAC 50/60 Hz, AC adapter (external)	100 - 240 V AC, 50/60 Hz, AC adapter (external)	100-240 VAC 50/60 Hz, AC adapter (external)
Near Real Time	Yes	Not mentioned	Yes
Remote Alarms	Yes	Yes	Yes
Remote Silencing	Yes	Yes	Yes (bedside device silences the central monitor)
Configuration of Thresholds	No (CEB is fixed at 95 and above)	Yes	Yes

Displays ECG Waveforms	Yes (3-4 leads minimum with remaining leads viewable with scroll feature)	Yes (1-2 leads)	Yes (up to 4 leads)
Number of Devices Displayed on Central Monitor	Up to 16	Up to 32	Up to 32
Extra Display Features	CEB, HR, up to 15 leads for rhythm monitoring, can display 15 lead ECG report, CEB graph, Voltage Time Data, Vector Loops, CEB/ECG/ Rhythm Reports	4 numerics	HR, SpO2, Pulse Rate, ST Segment Analysis, Arrhythmia detection
Use Environment:	Similar Not intended for home use	Similar Does not give info on Doctor Offices	Similar Not intended for home use

7. Testing and Conclusions:

Verification, validation and testing procedures were performed to assure that the new device works as was designed. Regression testing and latency supported the proposed label. The Vectraplex CMS is designed to meet the design specifications and was validated using multiple monitoring devices.

VectraCor has performed usability testing outlined in the Vectraplex CMS Usability Test Plan document. All performed testing was successful with no critical errors to report.

The maximum load test was done using 16 devices and 3 monitors over a single proxy agent. The average latency for this maximum load test was between 6 and 7 seconds.

VectraCor has determined, based on the performance testing, that the Vectraplex CMS conforms to the design specifications and is substantially equivalent to the predicate devices. The device, as designed, is as safe and effective as the predicate devices.